

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 EB-07 MED-03 /034 R

66610

DRAFTED BY: DHEW/FDA:JRWEINROTH, M.D.:AMS

APPROVED BY: OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EUR/CE:DANDERSON(INFO)

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R 032255Z NOV 75

FM SECSTATE WASHDC

TO AMEMBASSY BONN

UNCLAS STATE 260164

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, GW

SUBJ: FDA ADVISORY - INADEQUATE HEPATITIS B SURFACE ANTIGEN
(HBSAG) TESTING

1. FDA ADVISES THAT THE FOLLO-
WING ITEM IS BEING RECALLED FROM THE
MARKET:

PRODUCT: FROZEN SOURCE PLASMA (HUMAN) LABELED IN PART "XXXSOURCE
PLASMA (HUMAN)XBLEED NO.XXDONOR NO.XXNON-REACTIVE FOR HEPATITIS B
ANTIGEN BY RIA METHOD. STORE AT -20 DEGREES CENTIGRADE OR COLDERX
CAUTION: FOR MANUFACTURING USE ONLY. DO NOT USE IF EVIDENCE OF
THAWING.XPLASMA CORP. OF CLEARWATER, 534 CLEVELAND STREET,
CLEARWATER, FLORIDA 33515U.S. LICENSE NO.XXX". U.S. LICENSE NO.
ON UNITS IS 551.

LOT NUMBERS: ALL LOTS OF SOURCE PLASMA (HUMAN) MANUFACTURED SINCE
10/1/74 ARE UNDER RECALL.

MANUFACTURER:

PLASMA CORPORATION OF CLEARWATER
534 CLEVELAND STREET
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CLEARWATER, FLORIDA 33515

RECALLING FIRM:

AUTOMATED MEDICAL LABORATORIES, INC.
7501 N.W. 66TH STREET
MIAMI, FLORIDA 33166

THE RECALLING FIRM IS THE PARENT CORPORATION FOR PLASMA CORPORATION OF CLEARWATER.

REASON FOR RECALL:

THE RECALL IS BASED UPON FINDINGS OF FDA INSPECTIONS WHICH DISCLOSED INADEQUATE HEPATITIS B SURFACE ANTIGEN TESTING PROCEDURES/CONTROLS, POOR RECORD KEEPING, SHIPMENT OF HBSAG REACTIVE UNITS, ETC.

2. FOREIGN CONSIGNEE AS FOLLOWS:

HEMO-MED, A.G.
6000 FRANKFURT AM-MAIN NO. 1
RODENBERGWEG, WEST GERMANY

SHIPMENTS:

JULY 1975 2073.270 LITERS
AUGUST 1975 99 BOXES

3. POST IS REQUESTED TO DETERMINE IF FOREIGN CONSIGNEE HAS RECEIVED RECALL LETTER FROM AUTOMATED MEDICAL LABORATORIES, INC., SENT 10/10/75. IN ADDITION, HEMO-MED, A.G. HAS BEEN IDENTIFIED AS A BROKER; THEREFORE, FDA DESIRES THAT SPECIFIC INFORMATION BE OBTAINED IDENTIFYING THE SECONDARY CONSIGNEES TO WHICH THE PLASMA WAS REDISTRIBUTED FOR FURTHER MANUFACTURING. KISSINGER

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Message Attributes

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Disposition Case Number: n/a
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Margaret P. Grafeld
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06 JUL 2006

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